Health Information Technology (HIT) Policy Committee
Adoption/Certification Workgroup
February 25, 2010

Testimony of Jeffrey Shuren, Director of FDA's Center for Devices and Radiological Health

Thank you for the opportunity to participate in this Workgroup discussion and share the FDA's perspective on potential approaches to address HIT-related safety concerns. Taking a balanced public health approach, the FDA seeks to support the benefits that HIT can bring through improvements in individual patient care and the overall healthcare system, while also minimizing the risks that this technology can potentially create.

This statement describes: (1) the FDA's legal and regulatory authorities over medical devices and the approach we have taken with respect to HIT to date; (2) various safety issues that have been reported to the FDA and other unique challenges presented by HIT; and (3) possible approaches the FDA could take in the future to help address these concerns.

The FDA's Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health by assuring the safety, effectiveness, and quality of medical devices – including software devices – throughout the total product life cycle.

Under FDA regulations, medical device establishments must electronically register and list their devices with the agency. Additionally, device manufacturers must submit Medical Device Reports (MDRs), the agency's mechanism for reporting adverse events associated with devices on the market. Manufacturers are required to report to the FDA device-related deaths and serious injuries, and malfunctions that may, if they were to recur, result in death or serious injury. User facilities must report device-related deaths to the FDA and device manufacturers, and must report serious injuries to device manufacturers.

Further requirements apply to certain medical devices based on risk. For example, the FDA requires premarket review of medium- to high-risk devices, such as infusion pumps or heart valves. The agency may also require postmarket surveillance, including post-approval studies or device tracking, for particular types of devices.

To further monitor the safety of medical devices on the market, the FDA also collects information through voluntary reporting programs. Patients and practitioners may voluntarily submit adverse event reports through the FDA's MedWatch system. CDRH's Medical Product Safety Network (MedSun) allows for active surveillance of roughly 350 participating user facilities, all of which receive training in medical device adverse event reporting. Device-related adverse event reports from the MDR system, MedWatch, and MedSun are collected in a publicly available database and are subjected to both routine and ad hoc analyses within the agency. Because our adverse event data is available to the public, members of the private sector and academia may also use it conduct their own analyses and research.

Under the Federal, Food, Drug, and Cosmetic Act, HIT software is a medical device. Currently, the FDA mandates that manufacturers of other types of software devices comply with the laws and regulations that apply to more traditional medical device firms. These products include devices that contain one or more software components, parts, or accessories (such as electrocardiographic (ECG) systems used to monitor patient activity), as well as devices that are composed solely of software (such as laboratory information management systems). To date, FDA has largely refrained from enforcing our regulatory requirements with respect to HIT devices.

Nevertheless, certain HIT vendors have voluntarily registered and listed their software devices with the FDA, and some have provided submissions for premarket review. Additionally, patients, clinicians, and user facilities have voluntarily reported HIT-related adverse events. In the past two years, we have received 260 reports of HIT-related malfunctions with the potential for patient harm – including 44 reported injuries and 6 reported deaths. Because these reports are purely voluntary, they may represent only the tip of the iceberg in terms of the HIT-related problems that exist.

Even within this limited sample, several serious safety concerns have come to light. The reported adverse events have largely fallen into four major categories: (1) errors of commission, such as accessing the wrong patient's record or overwriting one patient's information with another's; (2) errors of omission or transmission, such as the loss or corruption of vital patient data; (3) errors in data analysis, including medication dosing errors of several orders of magnitude; and (4) incompatibility between multi-vendor software applications and systems, which can lead to any of the above.[1]

HIT devices present unique considerations, each of which has the potential to impact patient safety. HIT software applications do not typically operate as stand-alone devices. Instead, these products are interconnected with one another into networks of varying degrees of complexity. Additionally, HIT software is designed to be dynamic and adaptable. User facilities expect to have the ability to make configuration changes to meet their local needs.

The FDA recognizes the tremendous importance of HIT and its potential to improve patient care. However, in light of the safety issues that have been reported to us, we believe that a framework of federal oversight of HIT needs to assure patient safety. Any such framework would need to take into account the complex and dynamic nature of HIT systems. Given the FDA's regulatory authorities and analytical tools, we could potentially, at a minimum, play an important role in preventing and addressing HIT-related safety issues, thereby helping to foster confidence in these devices.

The FDA could consider a range of approaches for addressing HIT-related safety concerns.

One possible approach would be to focus on postmarket safety by requiring HIT device establishments to electronically register and list their HIT devices, and to submit Medical Device Reports (MDRs) to the FDA. Under this approach, HIT device manufacturers would be responsible for correcting identified safety issues. The FDA could also make use of our

[1] For specific examples of reported problems, see the Appendix.

authority to require postmarket surveillance or tracking for selected higher-risk devices, which would provide more detailed information about the use and potential safety risks associated with these products. The FDA could share our postmarket information with vendors, premarket certification bodies, and users to help improve the design of future products. The FDA would exercise our discretion to not enforce other applicable requirements.

A second possible approach would be to focus on manufacturing quality and postmarket safety by requiring HIT device manufacturers to comply with the requirements described above, and also to adhere to FDA's Quality Systems Regulation (QSR). QSR requires manufacturers to adhere to specific minimum guidelines to assure the quality and consistency of products on the market. For example, the regulation requires that device manufacturers establish procedures for handling complaints from users, and for correcting and preventing recurrence of problems.

According to QSR, all software devices must comply with appropriate design controls to reduce the potential for problems. Design controls are an interrelated set of practices and procedures that are incorporated into the design and development process of a device, in order to check for problems and make corrections in the design of the device before it is put into production. For example, manufacturers of software devices must establish and maintain procedures for verification and validation of their device design. Based on data collected through our postmarket safety authority, the FDA could recommend design controls that would mitigate the risks that are unique to HIT devices, such as those associated with multiple software products interfacing with one another as a part of a comprehensive HIT system, or those associated with user-facility-specific customization of HIT software after installation. Such design controls would help to preserve the ability of user facilities to innovate and tailor the installation and use of these devices to their practical needs, while reducing risks to patients. The FDA would exercise our discretion to not enforce other applicable requirements.

Under a third approach, the FDA would apply our traditional regulatory framework, in which HIT device manufacturers would be required to meet all the same regulatory requirements as other, more traditional devices, including risk-based premarket review. Through premarket review, the FDA could assess the safety and effectiveness of high- and medium-risk HIT devices before they go into market use. Additionally, the FDA could establish certain requirements for approval for selected products. For example, the FDA could require that manufacturers provide as prerequisites for approval a clear installation plan for a given HIT device, or a hazard analysis of risk associated with medical-facility-specific configuration. The FDA could also require postmarket studies or specific product labeling for particular HIT devices as conditions for approval.

By working both collaboratively with and in complement to our government partners, the FDA could help to mitigate risks to the public health while promoting innovation.

Appendix: Examples of Reported Adverse Events

Category	Examples
Errors of Commission	**Example 1:** An error occurred in software used to view and document patient activities. When the user documented activities in the task list for one patient and used the "previous" or "next" arrows to select another patient chart, the first patient's task list displayed for the second patient. **Example 2:** A nuclear medicine study was saved in the wrong patient's file. Investigation suggested that this was due to a software error. **Example 3:** A sleep lab's workstation software had a confusing user interface, which led to the overwriting and replacement of one patient's data with another patient's study.
Errors of Omission or Transmission	**Example 1:** An EMR system was connected to a patient monitoring system to chart vital signs. The system required a hospital staff member to download the vital signs, verify them, and electronically post them in the patient's chart. Hospital staff reported that, several times, vital signs have been downloaded, viewed, and approved, and have subsequently disappeared from the system. **Example 2:** An operating room management software application frequently "locked up" during surgery, with no obvious indication that a "lock-up" was occurring. Operative data were lost and had to be re-entered manually, in some cases from the nurse's recollection. **Example 3:** An improper database configuration caused manual patient allergy data entries to be overwritten during automatic updates of patient data from the hospital information system.
Errors in Data Analysis	**Example 1:** In one system, intravenous fluid rates of greater than 1,000 mL/hr were printed as 1 mL/hr on the label that went to the nursing / drug administration area. **Example 2:** A clinical decision support software application for checking a patient's profile for drug allergies failed to display the allergy information properly. Investigation by the vendor determined that the error was caused by a missing codeset. **Example 3:** Mean pressure values displayed on a patient's physiological monitors did not match the mean pressures computed by the EMR system after systolic and diastolic values were entered.
Incompatibility between Multi-Vendor Software Applications	**Example 1:** An Emergency Department management software package interfaces with the hospital's core information system and the laboratory's laboratory information system; all three systems are from

or Systems	different vendors. When lab results were ordered through the ED management software package for one patient, another patient's results were returned. **Example 2:** Images produced by a CT scanner from one vendor were presented as a mirror image by another vendor's picture archiving and communication system (PACS) web software. The PACS software vendor stipulates that something in the interface between the two products causes some images to be randomly "flipped" when displayed.

DEPARTMENT OF HEALTH & HUMAN SERVICES
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MEMORANDUM

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Date: February 23, 2010

From: Chuck McCullough
Biomedical Engineer
Division of Patient Safety Partnership
Office of Surveillance and Biometrics (OSB)
Center for Devices and Radiological Health (CDRH)

Karen Nast, RN, MS
Nurse Consultant
Division of Patient Safety Partnership
OSB/CDRH

Leslie C. Sweet, RN
Nurse Consultant, MDR Analyst
Product Evaluation Branch I (PEB I)
Division of Postmarket Surveillance (DPS)
OSB/CDRH

Subject: Health Information Technology (H-IT) Safety Issues

To: Jeff Shuren, MD, JD
Director, CDRH

Through: Doug Wood, Associate Director, DPS/OSB/CDRH
Marilyn Flack, Director, Division of Patient Safety Partnership

This report serves to characterize medical device reports (MDRs) in the Manufacturer and User Facility Experience (MAUDE) database, inclusive of MedSun reports, pertaining to Health Information Technology (H-IT) safety issues as requested by the Office of the Center Director, Center for Devices and Radiological Health (CDRH), in contrast to the previously submitted MedSun and Office of Compliance information.

Due to the inherent vast scope of H-IT safety issues and potential suspect devices, the current CDRH product code (procodes) list was screened to identify those procodes that would mostly likely capture the highest volume of pertinent MDRs (Table 1). The MAUDE database was then queried using these procodes and the Date Report Received "01-JAN-2008 to 18-FEB-2010." This search was further narrowed by performing a text search of 30 terms commonly utilized in H-IT safety reports (Appendix A), and then individually reviewing the MDRs to exclude unrelated reports. These combined queries yielded 257 MDRs, with identification of 3 additional procodes, highlighted in Table 1.

Table 1. Procodes Associated with the H-IT Safety Issue Search

Procode	Name	Count	Percent
LLZ	System, image processing, radiological	148	58
LNX	Medical computers and software	63	25
MMH	Software, blood bank, stand alone products	19	7
JQP	Calculator/data processing module, for clinical use	12	5
NSX	Software, transmission and storage, patient data	6	2
NZH	Medication management system, remote	3	1
IXW	Processor, radiographic-film, automatic	2	1
DQK	Computer, diagnostic, programmable	1	0.3
LMB	Device, digital image storage, radiological	0	
Procodes Revealed Following Search			
MHX	Monitor, physiological, patient (with arrhythmia detection or alarms)	1	0.3
JAK	Scanner, computed-tomography, x-ray; system, x-ray, tomography, computed	1	0.3
IWZ	Film, radiographic; film, x-ray, dental, extraoral; bitewing; film, x-ray, dental, intraoral; medical	1	0.3

Limitations of the MAUDE search and final subset of MDRs include the following:

1. Not all H-IT safety issue MDRs can be captured due to limitations of reporting practices including
    a. Vast number of H-IT systems that interface with multiple medical devices currently assigned to multiple procodes making it difficult to identify specific procodes for H-IT safety issues;
    b. Procode assignments are also affected by the ability of the reporter/contractor to correctly identify the event as a H-IT safety issue;
    c. Correct identification by the reporter of the suspect device brand name is challenged by difficulties discerning the actual H-IT system versus the device it supports.
2. Due to incomplete information in the MDRs, it is difficult to unduplicate similar reports, potentially resulting in a higher number of reports than actual events.
3. Reported death and injury events may only be associated with the reported device but not necessarily attributed to the device.

4. Correct identification by the reporter of the manufacturer name is convoluted by the inability to discern the manufacturer of the actual H-IT system versus the device it supports.
5. The volume of MDR reporting to MAUDE may be impacted by a lack of understanding the reportability of H-IT safety issues and enforcement of such reporting.

The majority of the MDRs were submitted by the manufacturer (Table 2), and the primary Type of Event was Malfunction (Table 3).

Table 2. Report Source

Report Source		Manufacturer	User Facility	Voluntary	Distributor
MDRs	Count	202	15	35	5
	%	78	6	14	2

Table 3. Type of Event

Type of Event		Death	Injury	Malfunction
MDRs	Count	6	43	208
	%	2	17	81

Review of the Device Problem Codes compared with individual review of the Event Narratives prompted the development of 12 detailed categories (Appendix C) to which the MDRs were assigned to more clearly classify the system malfunctions. These MDRs were then reassigned to more general categories, as defined in Appendix B. The majority of the events were categorized as Error of Commission (49%), with 27% as Errors of Omission and Transmission and 22% as Errors in Data Analysis (Table 4).

Table 4. H-IT Safety Issues-General Categories

Category	Description	Count	%
Errors of Commission (EOC)	Events such as accessing the wrong patient's record or overwriting one patient's information with another's	126	49
Errors of Omission or Transmission (EOT)	Events such as the loss or corruption of vital patient data	69	27
Errors in Data Analysis (EDA)	Includes medication dosing errors of several orders of magnitude	57	22
Incompatibility between Multi-Vendor Software Applications or Systems (ISMA)	Incompatibilities which can lead to any of the above	5	2

A review of the Top 10 Patient Problem Codes provided limited insight into the clinical impact of the reported events. This limitation may result from an absence of mandatory reporting regulations and requirements including manufacturer investigation of the event.

Individual review of the death reports resulted in 3 reports categorized as Error of Commission, 2 as Error of Omission or Transmission, and 1 as Error in Data Analysis (Table 5). Of note, the MedWatch Voluntary Reports were from the same reporter summarizing hospital-wide H-IT experience without an isolated incident or patient identified.

Table 5: Summary and Categorization of Death Reports

MFR	Brand	Event Summary	H-IT Safety Issue General Categories
GE Healthcare Integrated IT Solutions	Centricity RA1000	User entered wrong patient name on study image resulting in therapy administration to wrong pt	EOC
Stentor Incorporated, a Philips Medical Systems Company	ISITE PACS	Delay in network transmission of diagnostic image preventing administration of treatment prior to pt's death	EOT
Cerner Corporation	Cerner Millennium	Report sites shortfalls in hospital's implementation of CPOE system	EOT
Baxa Corporation	Abacus V2.0 Tpn Calculating Software	Pt chemotherapy inaccurately prepared	EDA
GE Healthcare Information Technologies	Centricity Enterprise Web	User unaware that an exam had a note attached containing positive clinical findings	EOC
Cerner Corporation	Millenium	Report sites shortfalls in hospital's implementation of CPOE and EHR systems	EOC

CPOE-Computerized Physician Order Entry; EHR-Electronic Health Records

In summary, the results of this data review suggest significant clinical implications and public safety issues surrounding Health Information Technology. The most commonly reported H-IT safety issues included wrong patient/wrong data, medication administration issues, clinical data loss/miscalculation, and unforeseen software design issues; all of which have varying impact on the patient's clinical care and outcome, which included 6 death and 43 injuries. The absence of mandatory reporting enforcement of H-IT safety issues limits the number of relevant MDRs and impedes a more comprehensive understanding of the actual problems and implications.

Management Review –

Douglas Wood, Associate Director, Division of Post Market Surveillance

After review of the information provided in this memorandum, I concur with the findings contained within this analysis.

Management Review –

Marilyn Flack, Director, Division of Patient Safety Partnerships

After review of the information provided in this memorandum, I concur with the findings contained within this analysis.

Appendix A
Text Search Terms

Keyword	# of Records with Keyword
Antivirus	0
Bar Code	1
Computer	59
Computer Virus	1
Conficker	1
CR Reader	8
Data	280
DICOM	23
Download	5
EMR	8
Health Record	0
HIS	1648
HL7	7
Information System	24
Interface	55
LAN	63
LIS	253
Malware	0
Microsoft Patch	1
Network	11
Operating System	2
PACS	277
Pharmacy Information System	2
Print	73
Re-Boot	2
Reboot	15
Software Patch	22
Transmit	31
Windows	4
Workstation	89

Appendix B
H-IT Safety Issues—Generalized Categories

Category	Examples
Errors of Commission (EOC)	**Example 1:** An error occurred in software used to view and document patient activities. When the user documented activities in the task list for one patient and used the "previous" or "next" arrows to select another patient chart, the first patient's task list displayed for the second patient. **Example 2:** A nuclear medicine study was saved in the wrong patient's file. Investigation suggested that this was due to a software error. **Example 3:** A sleep lab's workstation software had a confusing user interface, which led to the overwriting and replacement of one patient's data with another patient's study.
Errors of Omission or Transmission (EOT)	**Example 1:** An EMR system was connected to a patient monitoring system to chart vital signs. The system required a hospital staff member to download the vital signs, verify them, and electronically post them in the patient's chart. Hospital staff reported that, several times, vital signs have been downloaded, viewed, and approved, and have subsequently disappeared from the system. **Example 2:** An operating room management software application frequently "locked up" during surgery, with no obvious indication that a "lock-up" was occurring. Operative data were lost and had to be re-entered manually, in some cases from the nurse's recollection. **Example 3:** An improper database configuration caused manual patient allergy data entries to be overwritten during automatic updates of patient data from the hospital information system.
Errors in Data Analysis (EDA)	**Example 1:** In one system, intravenous fluid rates of greater than 1,000 mL/hr were printed as 1 mL/hr on the label that went to the nursing / drug administration area. **Example 2:** A clinical decision support software application for checking a patient's profile for drug allergies failed to display the allergy information properly. Investigation by the vendor determined that the error was caused by a missing codeset.

Category	Examples
	Example 3: Mean pressure values displayed on a patient's physiological monitors did not match the mean pressures computed by the EMR system after systolic and diastolic values were entered.
Incompatibility between Multi-Vendor Software Applications or Systems (ISMA)	**Example 1:** An Emergency Department management software package interfaces with the hospital's core information system and the laboratory's laboratory information system; all three systems are from different vendors. When lab results were ordered through the ED management software package for one patient, another patient's results were returned. **Example 2:** Images produced by a CT scanner from one vendor were presented as a mirror image by another vendor's picture archiving and communication system (PACS) web software. The PACS software vendor stipulates that something in the interface between the two products causes some images to be randomly "flipped" when displayed.

APPENDIX C
H-IT Safety Issues—Detailed Categories

Category	Description	Examples	Count (%)	H-IT Safety Issue General Categories
Wrong patient/wrong data	Event in which medical information is accessed by the healthcare provider and either the wrong patient or the wrong information is retrieved despite correct inquiry procedures.	Patient A data is requested but patient B data is received. Patient A data specific procedure data is requested, but procedure from a different date or time is provided.	100 (39)	EOC
Clinical data loss/miscalculation	Event in which medical information is either permanently or temporarily lost, deleted or overwritten, without a command to delete, or the scale of measure applied to the electronic data is inaccurate.	Patient A data is requested but no information is found. Forwarded Radiology results are not displayed in the recipient's message center. Standard uptake values for PET are incorrect when the exam is performed on another manufacturer's scanner.	19 (7)	EOC, EOT, EDA
Human factors/usability issues	Event in which the device design is confusing or likely to be misunderstood by user resulting in unanticipated, clinically-related errors.	Excessive drop down menu selections facilitating data entry error. Legibility is limiting. Device workflow is counterintuitive.	16 (6)	EOC
Unforeseen software design issues	Unforeseen event in which software design is attributed to safety issues.	System fails to return intake and output results. When an order is modified, the system displays the current and previous versions of the order.	18 (7)	EOT

Category	Description	Examples	Count (%)	H-IT Safety Issue General Categories
Image measurement/corruption issues	Event in which measurement algorithms or functions produced erroneous results or the image displays were corrupted.	Incorrect image sizing. Text misplaced over images.	13 (5)	EOT
Radiologic image misorientation	Event in which the image (e.g., x-ray, nuclear scans, etc) is labeled incorrectly or whose orientation is not correct.	Nuclear image is presented flipped (e.g., right-left reversed). Diagnostic image is flipped but the left-right markers are not.	12 (5)	EOT
Medication administration issues	Any event in which the device software design results in errors of medication administration.	Dosing errors based on calculations; duplication of orders.	20 (8)	EDA
Lab result issues	Any event in which the device software design results in erroneous lab results.	Lab results are not being tagged as "high" or "low." Critical lab results are not entered into the phone-alert cue.	17 (7)	EDA
System data versus printout data discrepancy	Event in which data printout is different from data records requested from the system.	IV fluid rates greater than 1,000ml/hr print as 1ml/hr on the label. Patient data other than what was selected printed out.	6 (2)	EDA
Charting/orders	Event in which clinical data (charting or orders) is not correctly stored, transferred, updated, or displayed in the medical records.	Automatic expiration of drug order not displayed. Inability to access expanded medication charts. Vital sign data does not populate the chart.	14 (5)	EOT

Category	Description	Examples	Count (%)	H-IT Safety Issue General Categories
Medication preparation issues	Any event in which pharmaceutical system produces erroneous guidelines for preparation and distribution of medications.	Incorrect drug dosage used to prepare infusion.	10 (4)	EDA
Other	Miscellaneous safety issues	Server crashes. Networking problems. Computer virus. Incorrect system configuration by user.	12 (5)	EOC, EOT, EDA, IMSA

EOC: Errors of Commission; EOT- Errors of Omission or Transmission; EDA- Errors in Data Analysis; IMSA- Incompatibility between Multi-Vendor Software Applications or Systems